occurs. This device is made of polytetrafluoroethylene or silicone elastomer.

(b) *Classification*. Class II.

§874.3850 Endolymphatic shunt tube with valve.

(a) *Identification*. An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve the symptoms of vertigo. The device directs excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. The function of the pressure-limiting inner ear valve is to impede the flow of endolymph so that a physiologically normal endolymphatic pressure is maintained. The device is made of silicone elastomer and polyamide and contains gold radiopaque markers within the silicone elastomer sheath.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See §874.3.

§874.3880 Tympanostomy tube.

(a) *Identification*. A tympanostomy tube is a device that is intended to be implanted for ventilation or drainage of the middle ear. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. A type of tympanostomy tube known as the malleous clip tube attaches to the malleous to provide middle ear ventilation. The device is made of materials such as polytetrafluoroethylene, polyethylene, silicon elastomer, or porous polyethylene.

(b) *Classification*. Class II.

§874.3930 Tympanostomy tube with semipermeable membrane.

(a) *Identification*. A tympanostomy tube with a semipermeable membrane is a device intended to be implanted for ventilation or drainage of the middle ear and for preventing fluids from entering the middle ear cavity. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. The tube portion of the device is made of silicone elastomer or porous polyethylene, and the membrane portion is made of polytetrafluoroethylene.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See §874.3.

Subpart E—Surgical Devices

§874.4100 Epistaxis balloon.

(a) *Identification*. An epistaxis balloon is a device consisting of an inflatable balloon intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.

(b) *Classification*. Class I.

§874.4140 Ear, nose, and throat bur.

(a) *Identification*. An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (§874.4250) for incising or removing bone in the ear, nose, or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996]

§874.4175 Nasopharyngeal catheter.

(a) *Identification*. A nasopharyngeal catheter is a device consisting of a bougie or filiform catheter that is intended for use in probing or dilating the eustachian tube. This generic type of device includes eustachian catheters.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996]